

Atty. Dkt. No. EPI3007B  
(formerly TSRI 184.2C2)

### REMARKS

After amending the claims as set forth above, claims 81-85, 87, 89-90 and 93-95 will be pending in this application. Claim 83 has been amended to clarify the invention for better understanding by the Examiner. No new matter has been added by these changes.

### OBJECTION TO CLAIM 83

Claim 83 is objected to because the word "polypeptide" is allegedly misspelled in line 13. Applicants respectfully disagree. "Polypeptide" is correctly spelled in line 13 and elsewhere throughout the claim. Further clarification of this objection is respectfully requested.

### REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claim 79 has been rejected under 35 U.S.C. § 112, first paragraph for allegedly lacking written description for the phrase "is present at a level of at least 56 ng/mg of total protein in extracts of said plants." The Examiner alleges that this phrase introduces new matter that goes beyond the specification that is alleged to cover only specific antibody fragments previously known in the art. The rejection is respectfully traversed. However, the rejection has been rendered moot in view of the cancellation of claim 79.

### REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The claims have been variously rejected under 35 U.S.C. § 112, Second Paragraph. Reconsideration of the rejections is respectfully requested in view of the amendments and remarks herein.

### Relevant Law

When determining definiteness, the proper standard to be applied is "whether one skilled in the art would understand the bounds of the claim when read in the light of the specification."

Atty. Dkt. No. EPI3007B  
(formerly TSRI 184.2C2)

*Credle v. Bond*, 30 USPQ2d 1911, 1919 (Fed. Cir. 1994). Recognizing that the English language is not always precise, the settled law has established that the essential inquiry in a definiteness analysis is whether the claims set out and circumscribe the claimed subject matter with reasonable particularity. *See, e.g.*, MPEP § 2173.02; *see also, Miles Laboratories, Inc. v. Shandon, Inc.*, 27 USPQ2d 1123, 1127 (Fed. Cir. 1993) (“If the claims read in the light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more.”) (emphasis added). Definiteness is not analyzed in a vacuum, but in light of the content of the specification, and with the knowledge available to the skilled artisan.

(1) Claim 83 has been rejected under 35 U.S.C. §112 as allegedly being indefinite because there is insufficient antecedent basis for the recitation “said polypeptide product” in line 5, 6-7 and in line 13. Reconsideration of the rejection is respectfully requested in view of the amendment of the claim.

(2) Claim 83 has also been rejected under 35 U.S.C. §112 second paragraph because there allegedly is insufficient antecedent basis for the recitation “said polypeptide product” in line 12-13. Reconsideration of the rejection is respectfully requested in view of the amendment of the claim.

(3) Claim 83 has also been rejected under 35 U.S.C. §112 second paragraph because there allegedly is insufficient antecedent basis for the recitation “said polypeptide product” in line 12-13. Reconsideration of the rejection is respectfully requested in view of the amendment of the claim.

(4) Claims 84 and 85 have been rejected under 35 U.S.C. §112 as allegedly being indefinite because the recitation “wherein said product comprising a single immunoglobulin polypeptide associates with a polypeptide to form a multimer” lacks support in the specification. The examiner states that the identity of the multimer is unclear. However, the rejection has been rendered moot in view of the cancellation of claim 84 and 85.

Atty. Dkt. No. EPI3007B  
(formerly TSRI 184.2C2)

(5) Claim 88 has been rejected under 35 U.S.C. §112 as being indefinite for failing to distinctly claim the recitation "wherein said product comprising a single immunoglobulin polypeptide comprises paratope". The examiner states that a paratope requires the presence of immunoglobulin light chain and an immunoglobulin heavy chain and that the instant invention is directed towards plant cells containing only heavy chain immunoglobulin peptides. However, the rejection has been rendered moot in view of the cancellation of claim 88.

(6) Claims 83, 79, 81-82, 84-85, 87, 89-90 and 93-95 have been rejected under 35 U.S.C. §112 as allegedly being indefinite in the recitation "wherein plant cells do not contain nucleic acid encoding said light chain". The examiner states that the rejection is maintained because it is unclear whether the plant cells do not contain any nucleic acid encoding the light chain, or whether the plant cells do not contain only the nucleic acid encoding the specific light chain from the particular antigen specific immunoglobulin from which the heavy chain is obtained. To clarify this point, the applicant has amended the claim to specify that the plant cells do not contain nucleic acid encoding "a" light chain.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is urged to contact the undersigned by telephone to address any outstanding issues standing in the way of an allowance.

Respectfully submitted,

Date: January 4, 2005

FOLEY & LARDNER LLP  
P.O. Box 80278  
San Diego, California 92138-0278  
Telephone: (858) 847-6700  
Facsimile: (858) 792-6773

By Barry S. Wilson  
Barry S. Wilson  
Attorney for Applicant  
Registration No. 39,431